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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,196	03/23/2000	ROGER JOHN DALY	1871-129	8868
6449	7590	01/30/2004	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			CHERNYSHEV, OLGA N	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/509,196	Applicant(s) DALY ET AL.	
	Examiner Olga N. Chernyshev	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-7,19-22,24-29 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-7,19-22,24-29 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claims 8-18 have been cancelled and claims 1 and 22 have been amended as requested in the amendment of Paper filed on November 19, 2003. Claims 1, 5-7, 19-22, 24-29 and 31 are pending in the instant application.

Claims 1, 5-7, 19-22, 24-29 and 31 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on November 19, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

5. Claims 1, 5-7, 19-22, 24-29 and 31 stand rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for reasons of record as applied to claims 1-7 in section 9 of Paper No. 12 and further for reasons of record in sections 9 of Paper No 12, section 6 of Paper No. 22 and section 7 of Paper No. 31. Briefly, the instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

At pages 6 and 7 of the Response Applicant argues that in accordance with The Utility Examination Guidelines the assertion of any practical utility is considered credible and further that it is improper to disregard the opinion of a qualified expert that is based upon relevant facts. There appears to be no disagreement with the Examiner's position. However, the issue at hand in the instant case remains that at the time of filing, the instant specification fails to disclose the specific, emphasis added, and substantial credible utility of the instant novel interacting protein 2.2412 encoded by the claimed isolated polynucleotide molecules. As fully and extensively explained in the appropriate sections of the previous office actions, the assertion that a novel 2.2412 protein encoded by the claimed polynucleotide is a candidate effector protein for the Grb7 proteins, which maybe associated with cancer, does not make the instant DNA or encoded protein diagnostic of cancer. There is no evidence of record presented in the instant specification, as filed that would allow using the claimed polynucleotides in detection of any cancer, including prostate or breast cancer.

Applicant submits on page 8 of the Response that "there is no such requirement in the MPEP, The Guidelines, or the law that requires "evidence or sound scientific reasoning" to be in a patent application to support an asserted utility. This argument has been fully considered but is not deemed to be persuasive for the following reasons.

According to legal standard, a specification can meet the utility and enablement requirement for a new polynucleotide as long as the specification discloses at least one credible, specific and substantial asserted utility for the new polynucleotide (an "evidence"), or a well-established utility for the claimed polynucleotide would be *prima facie* obvious to the skilled artisan ("sound scientific reasoning"). Thus, contrary to Applicant's statement, the law requires

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that the patent application describes the utility of the claimed invention based on evidence or obviousness to one skilled in the art. In the instant case, because the assertion of the utility of polynucleotides encoding 2.2412 protein as a tumor marker is not supported by any evidence of record, such as data showing differential expression of 2.2412 protein in healthy *versus* cancerous tissue, or a mutated form of a polynucleotide specifically associated with certain types of cancer, mere statement that “detection of the encoded protein should provide a useful tumour marker and/or prognostic indicator” (page 1, lines 4-5 of the instant specification) does not support such assertion. Therefore, one skilled in the art using the instant disclosure, as originally filed, would clearly not be able to diagnose any cancer due to the lack of critical information regarding specific association of 2.2412 and a particular type of cancer.

Applicant’s further argues that Declaration of Hitoshi provided “a credible association of 2.2412 expression and human cancers” (pages 8 and 9 of the Response). These arguments have been fully and extensively answered before in the previous office actions. Briefly, 35 USC § 101 clearly states that the invention must be useful in currently available form, which precludes any further experimentation to establish the utility of the claimed invention. Thus, the asserted utility cannot be supported based on the subsequent discovery that 2.2412 was expressed at significantly higher levels in two types of lung cancer and in three types of breast cancer. Again, the instant specification, as filed, fails to provide any information regarding using novel 2.2412 sequences as a specific marker for breast and lung cancer. General suggestion that 2.2412 protein can be used as a tumor marker does not stand for assertion of specific substantial and credible utility. Moreover, the instant specification clearly indicates that the novel 2.2412 is broadly expressed in all normal tissues, except kidney cells (page 10, second paragraph), which would

lead to a conclusion that the at the time of the invention 2.2412 could clearly not be used as a tumor marker.

Thus, because the instant specification does not disclose a specific, substantial and credible “real world” use for the claimed novel polynucleotide sequences encoding 2.2412 protein in their currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

6. Claims 1, 5-7, 19-22, 24-29 and 31 also stand rejected under 35 U.S.C. 112, first paragraph for reasons of record as applied to claims 1-7 in section 10 of Paper No. 12 and further for reasons of record in section 7 of Paper No. 22 and section 8 of Paper No. 31.

9. Claims 1, 5-7, 20, 22, 24-26 and 28, as amended, stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record as applied to claims 1-3 in section 12 of Paper No. 12 and further for reasons of record in section 8 of Paper No. 22 and section 9 of Paper No. 31.

Applicant argues that not all claimed species have to be specifically described in the specification and submits at page 11 of the Response “{o]therwise, to claim a genus, every species within a genus would have to be explicitly described. That is not the law”. However, Applicant has mischaracterized the Examiner’s position. The instant specification fails to satisfy written description requirement because it does not provide any disclosure regarding critical

relationship between structure and function of the instant claimed polynucleotides. It is not clear which nucleic acids in SEQ ID NO: 2 are critical to encode a polypeptide, which is asserted to be a tumor marker and “that binds Grb7” and which nucleic acids are expendable. Therefore, there is no analogy between Example 14 of the Synopsis and the instant situation, contrary to Applicant’s argument (bottom at page 11 of the Response). Because the instant specification fails to provide information regarding biological activity of the protein encoded by the claimed polynucleotides, one skilled in the art would not know “how to assay for measuring the activity of the protein” (bottom at page 11 of the Response). Furthermore, because the instant specification provides no disclosure regarding nexus between “binding to Grb7” and “tumor marker”, measurement of binding activity of protein with 95% identity to 2.2412 protein of SEQ ID NO: 2, encoded by different claimed species of SEQ ID NO: 1, clearly does not support analogy between instant case and the case disclosed in Example 14.

Therefore, for reasons fully explained earlier and reasons of record in the instant office action, the claims are directed to subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Conclusion

7. No claim is allowed.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original

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signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-7939. Official papers should NOT be faxed to (703) 308-7939.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D. *OC*



JOHN ULM
PRIMARY EXAMINER
GROUP 1800